October l, 1990

VETERINARY BIOLOGICS MEMORANDUM NO. 800.79

Subject: Submission of Serum Samples for In Vitro Potency Tests

To: Biologics Licensees, Permittees, and Applicants
Director, National Veterinary Services Laboratories
Directors, VS Regions
Deputy Director, Veterinary Biologics Field Operations

I. PURPOSE

To provide procedures for selecting, authorizing, and submitting serum samples to the National Veterinary Services Laboratories (NVSL) from host animals used in the potency evaluation of biological products.

II. BACKGROUND

Tests of biological products are specified in Title 9, Code of Federal Regulations (9 CFR), Part 113.6. The Standard Requirements in 9 CFR, Part 113, provide for the submission of serum samples from host animals used in potency tests for confirmatory testing according to the Outline of Production or Standard Requirement. Compliance with this memorandum should expedite serial release testing and preclude the use of additional host animals in evaluating the potency of biological products.

III. SAMPLE SUBMISSIONS

A. At least one (1) sample of pre-vaccination and post-vaccination serum from each animal used in the Standard Requirement or Outline of Production potency test for each serial should be submitted at the same time. The minimum sample size is 4 ml for each sample.

B. The firm's official sampler should authenticate the origin of the serum samples, their packaging, and the shipment of the samples to NVSL. Verification of bleeding procedures, blood processing, and in-house test results will be the responsibility of the firm's Animal Testing and Quality Control personnel. Samples should be submitted in accordance with Veterinary Services Memorandum 800.59.

C. The National Veterinary Services Laboratories has two (2) weeks upon receipt of such samples to initiate confirmatory testing.

D. The standard serological test designated in the Standard Requirement or the firm's Outline of Production should be used.

IV. INTERPRETATION OF TEST RESULTS

When unsatisfactory test results are obtained at NVSL following satisfactory test results by the firm, NVSL will repeat the serological assays. If this does not resolve the discrepancy in test results, the firm will be requested to complete a second host animal potency test prior to repeat testing at NVSL. If a second host animal test is not done, the serial(s) will be considered unsatisfactory.

/s/

Terry L. Medley, J.D.
Director